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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,680	10/31/2001	Paul L Feldman	PU3318USw	6805

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/980,680	Applicant(s) FELDMAN ET AL	
	Examiner Brenda L. Coleman	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-17,19,20,24-26,28-32 and 34-37 is/are pending in the application.
- 4a) Of the above claim(s) 15-17,19,20,26,30,31,36 and 37 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4,5,8,9,28,29,34 and 35 is/are allowed.
- 6) ☒ Claim(s) 1,6,7,10,24,25 and 32 is/are rejected.
- 7) ☒ Claim(s) 11-14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 4-17, 19, 20, 24-26, 28-32 and 34-37 are pending in the application.

This action is in response to applicant's amendment filed November 26, 2003.

Claims 2, 3 and 33 have been canceled and claims 1, 4-7, 9, 24, 25, 28-30 and 37 have been amended.

Response to Amendment

Applicant's amendments filed November 26, 2003 have been fully considered with the following effect:

1. Claims 15-17, 19, 20, 26, 30, 31, 36 and 37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 8.
2. With regards to the rejection of Claims 1, 24 and 32 as being drawn to an improper Markush group in the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicant's stated that the various members defining the variables R⁴, R⁵ and R⁶ are not members of an art-recognized class, the compounds as a whole share a common structural feature, namely the benzodiazepine ring structure, disclosed as essential to the disclosed utility of the compounds.

In re Weber 198 USPQ 328 states that a Markush-type claim is directed to independent and distinct inventions, is two or more of its members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the

members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). Weber goes on to state in the next paragraph that if the claim is of that nature, the examiner is authorized to reject it as an improper Markush claim and for misjoinder under 35 U.S.C. 121 and to require the applicant to restrict the application to a single invention.

A reference anticipating one invention, would not render obvious the others, for example a benzodiazepine ring is different from triazolobenzodiazepine, pyrrolobenzodiazepine, imidazobenzodiazepine, etc. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The elected invention which was examined in pending claims 1, 4-14, 24, 25, 28, 29, 32, 34 and 35, is drawn to compounds, compositions and method of use of the compounds of formula I where the ring is a benzodiazepine ring.

Claims 1, 24 and 32 are rejected as being drawn to an improper Markush grouping. For reasons of record and stated above.

3. With regards to the objection to the specification under 35 U.S.C. § 132 of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicants stated that paragraph 3, lines 5-25 is amended to replace "pyridylC₁₂alkyl, imidazolylC₁₋₂alkyl" with the recitation: "4-pyridylmethyl, 4-

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pyridylethyl, 4-imidazolylethyl". However, the applicant's failed to indicate the support for the specific amendment. Additionally, the definition of R^7 does not included the specific moieties described in the specification with respect to formula (I). The definition of R^7 in the species of claim 11 is part of a list of species with specific variables, not the description of the genus of formula I. Additionally, recent case law *Tronzo v. Biomet* 47 USPQ2d 1829 states that a species in a prior application does not provide written description to a generic claim.

4. The applicant's amendments are sufficient to overcome the objection to the specification labeled paragraph 5) of the last office action, which are hereby **withdrawn**.

5. With regards to the 35 USC § 112, first paragraph rejection of claims 1, 10, 24, 25 and 32 of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicants stated that the foregoing amendment to claim 1 replacing "pyridylC₁₂alkyl, imidazolylC₁₋₂alkyl" with the recitation: "4-pyridylmethyl, 4-pyridylethyl, 4-imidazolylethyl" overcomes this rejection. However, the applicant's failed to indicate the support for the specific amendment. Additionally, the definition of R^7 does not included the specific moieties described in the specification with respect to formula (I). The definition of R^7 in the species of claim 11 is part of a list of species with specific variables, not the description of the genus of formula I. Additionally, recent case law *Tronzo v. Biomet* 47 USPQ2d 1829 states that a species in a prior application does not provide written description to a generic claim.

Claims 1, 10, 24, 25 and 32 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way

as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For reasons of record and stated above.

6. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections of claims 3, 6, 7, 24, 25, 28, 29, 34 and 35 of the last office action, which are hereby **withdrawn**.

7. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejections labeled paragraphs 8), 9), 10), 11), 12), 13), 14), 16), 17), 18), 19) of the last office action, which are hereby **withdrawn**.

With regards to the 35 U.S.C. § 102, anticipation rejection of claim 1 labeled paragraph 15) of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicants stated that "removing the recitation of (1) R⁴ is H, a C₁-C₄alkyl, or a dialkylaminoalkyl and R⁵ and R⁶ together represent a single oxygen or S atom.... overcomes all of these rejections. However, this is not so where R¹ is benzyl; R² is phenyl; R³ is H; R⁴ and R⁵ together form a double bond and R⁶ is NH(CH(CH₃)(CH₂OH)); W is H; X is NH; n is 1; m is 0; and p is 0. (See example 15, Registry No. 170228-05-4 and 170227-96-0)

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Bock et al., U.S. Patent No. 5,834,464. For reasons of record and stated above.

In view of the amendment dated November 26, 2003, the following new grounds of rejection apply:

Specification

8. The disclosure is objected to because of the following informalities: the amendment to the paragraph on page 3, lines 5-25 does not state the definition of Y in the alternative.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 6 and 7 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility. The invention as claimed herein where the variable n of the structure of formula (I) is 2 is not described in the specification and thus there is no statement of utility for the compounds where n is 2 as shown by 4 species of claim 6 and 3 species of claim 7.

10. Claims 6 and 7 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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11. Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 6 and 7 are vague and indefinite in that it is not known what is meant by the variable M in the table. There is no variable M in formula (I).

Claim Objections

12. Claims 11-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

13. Claims 4, 5, 8, 9, 28, 29, 34 and 35 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00 Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting -SPE of 1624 at 571-272-0661.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda Coleman
Primary Examiner Art Unit 1624
February 9, 2004